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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,885	03/15/2000	Michael L. Nuccio	4300.012700	9507

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 08/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/525,885	NUCCIO ET AL.	
	Examiner	Art Unit	
	Elizabeth McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36,39-42 and 77-98 is/are pending in the application.
- 4a) Of the above claim(s) 14-36,84-93,96 and 97 is/are withdrawn from consideration.
- 5) Claim(s) 98 is/are allowed.
- 6) Claim(s) 1-7,9-13,39-42,77-83,94 and 95 is/are rejected.
- 7) Claim(s) 8 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

The amendment filed May 20, 2002 has been entered.

Applicants have pointed out the omission of a claim 19. Since the claim numbers must be consecutive, the claims and all claim dependencies have been renumbered by Rule 126 amendment. In addition, the claims referred to in the first office action and in applicants' 5 response have also been amended to reflect the proper claim numbering. Applicants should make the appropriate corrections in their file to avoid any confusion. From this point forward the claims will be referred to as they are renumbered.

Claims 1 and 9-13 are newly amended.

Claims 77-98 are newly submitted.

10 Claims 37, 38 and 43-76 have been deleted.

This application contains claims 14-36, 84-93, 96 and 97 drawn to an invention nonelected without traverse in Paper No. 9; and claims 1-13, 39-42 that recite non-elected invention(s), which are additional sequences, that were nonelected without traverse in Paper No.

9. A complete reply to the final rejection must include cancelation of nonelected claims and the 15 cancellation of non-elected inventions or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants assert that that the restriction requirement should be withdrawn, given that a generic claim (claim 8) has been held allowable. Therefore, rejoinder of the species claims is required.

20 The Examiner maintains that the restriction requirement was made FINAL in the last office action. In addition, applicants election was made without pointing out the supposed errors

in the restriction, and therefore, is treated as an election without traverse (see MPEP 818.03(c)). Furthermore, claim 8 is not generic but is limited to the elected invention of SEQ ID NO: 2, and the other sequences provided in the claims are nonelected *inventions*, not nonelected species, as applicants have stated.

5

Claims 1-13, 39-42, 77-83, 94, 95 and 98 are drawn to the elected invention of Group I and SEQ ID NO:2 and have been examined on the merits.

Claims 1-13, 39-42 are still objected to for reciting limitations drawn to non-elected inventions. A full response to the final rejection must include amendment of the claims to delete 10 the nonelected inventions, as stated above.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 Claims 9-13 and claim 95 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claims 9-13 and claim 95 (newly submitted) are indefinite in the recitation of “at least about”, given that it is unclear what range is covered by the term “about”. Therefore, it remains unclear what the lower limit of the range would actually be, as stated in the last office action.

Applicants' arguments filed May 20, 2002 have been fully considered but they are not persuasive. Applicants argue that "at least about" is definite and sets forth the scope of the claims, and that "about" is the same as saying "approximately". In addition, applicants assert "at least about" is commonly used in the biotechnological arts, including in numerous patents with 5 regards to the percent identity of sequences.

The Examiner maintains the rejection given that it remains unclear what constitutes the metes and bounds of "about" or "approximately" with regard to the percent identity of a sequence in the present application, and the specification fails to further define or clarify what range would be encompassed by this phrase. Amendment of the claims by deleting "about" would overcome 10 the rejection.

Claims 1-7, 9-13, 39-42, and claims 77-83, 94 and 95 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the 15 inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last office action.

Claims 1-7, 9-13, 39-42, and claims 77-83, 94 and 95 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for one 20 sequence from spinach, designated PEAMT (encoding SEQ ID NO: 2), that has PEAMT activity (see pages 90-91 of the specification) does not reasonably provide enablement for any gene that

encodes an enzyme that exhibits PEAMT activity that comprises at least 27 contiguous amino acids of SEQ ID NO:2 or is at least 85% identical to SEQ ID NO:2, for the reasons set forth in the last office action.

5 Applicants' arguments filed May 20, 2002 have been fully considered but they are not persuasive. Applicants argue that the rejections of the claims under 35 U.S.C. 112, first paragraph for lack of adequate written description and for lack of enablement should be withdrawn given that since the language of claim 1 is in the alternative that not all of the claimed polynucleotides need encode a functional polypeptide, and these sequences can function in another manner, such as use as a primer. Applicants point out that only parts (a) and (b) of claim 10 1 require that the claimed polynucleotides encode enzymatically functional protein. In addition, applicants assert that the specification provides detailed guidance regarding how to identify a polypeptide with PEAMT activity, and therefore the disclosure is enabling. Also, applicants assert that the claimed DNA sequences have numerous practical uses other than coding for the 15 enzyme, so the requirement to make and use is enabled. Applicants conclude that the use of PEAMT sequences in a variety of embodiments is well described and argue that any experimentation required would be routine, citing *In re Wands*. Applicants argue that embodiments include SEQ ID NO: 2 and SEQ ID NO: 4, as well as SEQ ID NO: 1 and SEQ ID NO: 3, as well as 85% identical sequences and portions of said sequences with contiguous amino acid sequences, as well as methods to isolate and identify others within the scope of the claims. 20

The Examiner maintains that the rejection is proper, given that parts (a) and (b) of claim 1 are the only portions of claim 1 that are under examination, as the other parts of the claim are drawn to nonelected inventions, which must be cancelled in response to the final rejection. Therefore, the claims under examination are drawn to sequences that encode a functional enzyme activity. In addition, there is no indication that the presence of the other sequences (SEQ ID Nos: 5 1, 3 and 4) support the enablement of claims to sequences that are 85% identical to SEQ ID NO: 2 or to sequences that would hybridize under stringent conditions to SEQ ID NO: 2.

See *Ex parte Formal* 230 USPQ 546 (PTO Bd. App. Int. 1986), where it was taught "the disclosure of a patent application must enable the practice of the invention claimed without 10 undue experimentation", wherein factors involved in the determination of undue experimentation were deemed to include "the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art and the breadth of the claims". Also see *Ex parte Hitzeman*, 9 USPQ 2d 15 1821, 1823 (PTO Bd. App. Int. 1988), where the unpredictable physiological art was deemed to require more than one embodiment for the enablement of broad claims.

In addition, the instant fact pattern closely resembles that in *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992). In *Ex parte Maizel*, the claimed invention was directed to compounds which 20 were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in *Ex parte Maizel* was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of

enablement set forth in the patent application. Even though Appellant in *Ex parte Maizel* urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic 5 functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. Clearly, a single disclosed sequence does not support claims to any nucleic acid hybridizing to same, given the lack of guidance regarding what sequences would hybridize specifically to SEQ ID NO: 1, and not other, related sequences.

10 Furthermore, see *Fiers* 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". In the present case only one full length sequence has been described, which is not sufficient to describe the entire genus claimed, including portions of the full length sequence 15 that would retain enzyme activity.

Therefore, the rejections of the claims under 35 USC 112, first paragraph, both for lack of enablement and for lack of written description are maintained.

20 Claim 8 is objected to for depending on a rejected base claim, but would be in condition for allowance if written in independent form, as stated in the last office action.

Claim 98 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE 5 MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, 10 will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

20 Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475, or to the Group receptionist whose telephone number is (703) 308-0196.

25 Elizabeth F. McElwain, Ph.D.
July 26, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

